K003186

Bard Interventional Products Division
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7031
Billerica, MA 01821-7031
978-663-8989

JAN - 9 2001

BARD

VI 510(k) SUMMARY SAFETY AND EFFECTIVENESS INFORMATION

As required by the Safe Medical Devices Act of 1990, codified under Section 513, Part (i)(3)(A) of the Food Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based follows.

A. Submitter Information

Submitter's Name:	Bard Interventional Products C.R. Bard, Inc.
Address:	129 Concord Road, Bldg. #3 Billerica, MA 01821
Phone:	978 - 262 - 4866
Fax:	978 - 262 - 4878
Contact Person:	Beth A. Zis, R.A.C.
Date of Preparation:	September 21, 2000

B. Device Name

Trade Name:	BARD® memotherm® Endoscopic Biliary Stent
Common/Usual Name:	Expandable, metallic biliary stent
Classification Name:	Biliary Stent, Biliary Catheter and Accessories

C. Predicate Device Name(s)

Trade Name:	BARD® memotherm-FLEXX™ Biliary Stent Bard Periphereal Technologies, Division of C. R. Bard, Inc.
	Ultraflex™ Diamond Biliary Stent System Microvasive® Boston Scientific Corp.

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D. Device Description:

The BARD® memotherm® Endoscopic Biliary Stent is comprised of two components – a self-expanding implantable metal stent and the delivery system. The stent is a nitinol grid-like cylinder with flared ends, available in 8 and 10mm diameters in 40, 60, 80 and 100mm lengths. While mounted on the deployment system the stent is compressed. Upon release of the stent from the deployment system the nitinol cylinder expands. The coaxial deployment system consists of an inner catheter, an outer sheath and an ergonomically shaped handgrip. Female luer injection ports are included on the back of the handgrip and ratchet carriage. Radiopaque markers are positioned on the deployment system to mark both ends of the stent.

E. Intended Use:

The BARD® memotherm® Endoscopic Biliary Stent is indicated for palliative treatment of patients with malignant biliary strictures.

F. Technological Characteristics Summary:

The proposed endoscopic biliary stent is a metal stent constructed of biocompatible nitinol. The self-expanding stent is packaged pre-mounted on a disposable delivery system that uses a uni-directional, pistol grip handle release mechanism.

The proposed endoscopic biliary stent is substantially equivalent to the BARD® memotherm-FLEXX™ Biliary Stent and the Ultraflex™ Diamond Stent System. All three of these devices are manufactured with a delivery system that implants a self-expanding metal stent over a guidewire using a coaxial, interfacing inner catheter and outer sheath.

Both the proposed endoscopic biliary stent and the memotherm-FLEXX Biliary Stent use the identical stent. They are both constructed from a grid like cylinder of nitinol and

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manufactured using the same processes and technology by Bard-Angiomed.

All three of these devices are intended for the palliative treatment of biliary strictures resulting from malignant neoplasms.

G. Performance Data

Biocompatibility tests were completed that demonstrate the device is safe for its intended use and patient population.

Comparative performance testing was done, as recommended by FDA's *Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents,* between the BARD® memotherm® Endoscopic Biliary Stent the BARD® memotherm-FLEXX™ Biliary Stent and the Ultraflex™ Diamond Biliary Stent System. This testing demonstrated through trackability/deployment and tensile testing that the proposed BARD Endoscopic Biliary Stent can safely be delivered and deployed to the desired location for its intended use.

Dimensional verification and expansion/compression forces all met the performance requirements, demonstrating that the memotherm Endoscopic Biliary Stent is substantially equivalent to both the BARD memotherm-FLEXX Biliary Stent and the Ultraflex Diamond Stent System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Beth A. Zis, R.A.C.
Manager of Regulatory Affairs
Bard Interventional Products Division
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7031
BILLERICA MA 01821-7031

Re: K003186
Bard® memotherm® Endoscopic Biliary Stent
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: October 10, 2000
Received: October 11, 2000

Dear Ms. Zis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003186

Device Name: Bard® memotherm® Endoscopic Biliary Stent

FDA's Statement of the Indications For Use for device:

The Bard® memotherm® Endoscopic Biliary Stent is indicated for palliative treatment of patients with malignant biliary strictures.

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

David G. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003186